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Exhibit R-2, RDT&E Budget Item Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

Appropriation/Budget Activity 0400: <i>Research, Development, Test & Evaluation, Defense-Wide / BA 2: Applied Research</i>	R-1 Program Element (Number/Name) PE 0602384BP / <i>CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)</i>
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
Total Program Element	-	189.042	209.956	256.197	-	256.197	248.726	233.847	227.596	235.192	Continuing	Continuing
MT2: <i>Mitigate (Applied Research)</i>	-	0.000	0.000	75.411	-	75.411	71.705	68.483	64.502	70.651	Continuing	Continuing
PT2: <i>Protect (Applied Research)</i>	-	0.000	0.000	58.758	-	58.758	59.338	59.855	61.517	63.612	Continuing	Continuing
UN2: <i>Understand (Applied Research)</i>	-	0.000	0.000	122.028	-	122.028	117.683	105.509	101.577	100.929	Continuing	Continuing
CB2: <i>Chemical Biological Defense (Applied Research)</i>	-	95.517	104.362	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	199.879
TM2: <i>Techbase Medical Defense (Applied Research)</i>	-	93.525	105.594	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	199.119

A. Mission Description and Budget Item Justification

This program element (PE) resources Applied Research across the Mitigate, Protect, and Understand portfolios. Chemical and Biological Defense Program (CBDP) investments provide an integrated, layered capability to enable combating weapons of mass destruction (CWMD) missions ranging from combat operations to Department of Defense (DoD) support to domestic incident prevention and response. The Projects in this PE support applied research in the areas of physical technologies, non-traditional agent (NTA) medical and physical defense technologies, and medical technologies. These investments are a key component to sustaining the core physical and intellectual chemical and biological (CB) defense infrastructure of the Department and support delivery of capabilities, assessments of emerging threats, and the ability to surge unique capabilities in response to a CB event. FY23 funding accelerates characterization and situational awareness of emerging biothreats and accelerates delivery of improved protection from and mitigation of biothreats, including rapid repurposing of available therapeutics and development of new vaccines.

Individual projects include:

- Mitigate (MT2): Improvement of CB defense material, including contamination avoidance, and decontamination. Development of drug treatments, therapeutics, patient decontamination technologies and individual protection advancements.
- Protect (PT2): Development of antidotes, disease surveillance medical technologies, vaccines, and, nerve agent pretreatments. Improvement of protection technologies and biological weapon/agent surveillance.
- Understand (UN2): Development of next generation chemical and biological hazard detectors, point-of-need diagnostic devices, and next generation diagnostics systems.

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- Chemical Biological Defense (CB2) and Techbase Medical Defense (TM2) are no longer active FY23 Projects due to budget restructure.

CBDP Science and Technology (S&T) Applied Research Stakeholders: U.S. Army Combat Capabilities Development Command Chemical Biological Center (DEVCOM CBC), United States Army Medical Research Institute of Infectious Diseases (USAMRIID), United States Army Medical Research Institute of Chemical Defense (USAMRICD), United States Army Natick Soldier Systems Center, Naval Research Lab (NRL), Air Force Research Lab (AFRL), among others. The intent is to maintain strategic partnerships with the DoD Service communities for mission success across the enterprise through collaborative planning and programming maintaining budget assurance.

The FY 2022 funding request was reduced by \$-1.931 million to account for the availability of prior year execution balances.

Efforts under this PE will transition to or will provide risk reduction for Advanced Technology Development (PE 0603384BP), Advanced Component Development and Prototypes (PE 0603884BP), and System Development and Demonstration (PE 0604384BP) activities.

B. Program Change Summary (\$ in Millions)	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total
Previous President's Budget	201.807	206.956	0.000	-	0.000
Current President's Budget	189.042	209.956	256.197	-	256.197
Total Adjustments	-12.765	3.000	256.197	-	256.197
• Congressional General Reductions	-	-			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	0.000	3.000			
• Congressional Directed Transfers	0.000	-			
• Reprogrammings	-8.065	-			
• SBIR/STTR Transfer	-4.700	-			
• Other Adjustments	0.000	-	256.197	-	256.197

Congressional Add Details (\$ in Millions, and Includes General Reductions)

Project: TM2: *Techbase Medical Defense (Applied Research)*

Congressional Add: *Biological Warfare Defense Therapeutics*

	FY 2021	FY 2022
	-	3.000
Congressional Add Subtotals for Project: TM2	-	3.000
Congressional Add Totals for all Projects	-	3.000

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Change Summary Explanation Funding: FY 2021 (-\$8.065 Million): Below threshold reprogramming to increase advanced development programs for implementation of common CBRN integrated systems architecture within the CBRN Integrated Early Warning (CBRN IEW) program, Joint Biological Tactical Detection System (JBTDSD) program test and evaluation, and Man Portable Diagnostic System (MPDS) product development. FY 2021 (-\$4.700 Million): Transfer of funding to support Small Business Innovative Research/Small Business Technology Transfer efforts. FY 2022 (+\$3.000 Million): Congressional Add for tularemia medical countermeasure. FY 2023: Funding increase reflects the fact that the FY 2022 President's Budget request did not include out-year funding. Funding includes specific increases for enhanced biodefense and pandemic preparedness investments (+\$35.500 Million), prophylaxis treatments for biological and emerging threats (+\$6.192 Million), collective protection efforts (+\$3.544 Million), and Departmental inflation rate adjustments (+\$1.456 Million). Schedule: N/A Technical: N/A		

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 2					R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				Project (Number/Name) MT2 / Mitigate (Applied Research)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
MT2: Mitigate (Applied Research)	-	0.000	0.000	75.411	-	75.411	71.705	68.483	64.502	70.651	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Mitigate Applied Research Project emphasizes the ability to conduct decontamination and medical actions that enable the quick restoration of combat power, maintain/recover essential functions that are free from the effects of Chemical, Biological, Radiological, and Nuclear (CBRN) hazards, and facilitate the return to pre-incident operational capability as soon as possible.

Thrust Areas included in this Project are:

- (1) Chemically Reactive Ocular Wound and Dermal Therapeutics (CROWD)
- (2) Enabling Science
- (3) Pharmaceutical Based Agents (PBA)
- (4) Reactivators of AChE as Therapeutics (ReACT)
- (5) Enhanced Survivability Coatings
- (6) Equipment Decontamination
- (7) Personnel Decontamination
- (8) Multifunctional Materials for Protection
- (9) Biological Warfare Defense Therapeutics

Chemically Reactive Ocular Wound and Dermal Therapeutics (CROWD): Develops a fielded medical countermeasure for the Warfighter that can treat a chemical agent that has breached the skin. The purpose of this effort is to collect the data that the Food and Drug Administration (FDA) will require for approval.

Enabling Science: Leverages technological advances and innovative approaches that will improve the time to develop and field chemical medical countermeasures (MCM) to the Warfighter. The thrust area aims to modernize the chemical MCM development process to allow for an earlier assessment of both the safety and efficacy of candidate therapeutics before regulatory submission and to cultivate technologies that enable development efforts across other medical portfolios to improve the ability to conduct MCM testing more cost-effectively with fewer animals.

Pharmaceutical Based Agents (PBA): Assesses candidate MCM and transitions them to partner United States Government entities for development into fieldable drug products. Activities focus on assessing current therapeutic drugs for protection against opioid agents and developing MCMs to treat non-opioid sedatives.

Reactivators of AChE as Therapeutics (ReACT): Develops broad-spectrum, centrally-acting acetylcholinesterase (AChE) reactivators, that increase survival, reduce morbidity, and decrease neurological damage. Two advanced lead candidates are in development.

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Enhanced Survivability Coatings: Addresses military equipment coating ease of decontamination and resistance to chemical agent penetration. Projects will develop temporary coatings that resist chemical agent absorption and are quickly decontaminated in the field and allow the rapid regeneration of combat power.

Equipment Decontamination: Addresses the limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; sensitive equipment, and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards, enable unit-level decontamination with rapid unmasking, reduce logistic needs, enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use, and to develop improved test methods.

Personnel Decontamination: Develops decontaminants with lower lifecycle costs and storage constraints and determine of time, efficacy and logistics burdens to Warfighters for mass casualty decontamination.

Multifunctional Materials for Protection: Discovers, develops, and integrates novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants that reactively decontaminate chemical warfare agents.

Biological Warfare Defense Therapeutics: Discovers broad-spectrum bacterial, toxin and viral therapeutics, and label expansion (repurposing) of medical countermeasures that are FDA approved or in advanced stages of clinical development. These efforts are coordinated with Department of Health and Human Services (HHS), Biomedical Advanced Research and Development Authority (BARDA), and across the interagency and Department, to leverage public and force/defense health related investments made to minimize risk and speed approval of novel antibiotic countermeasures.

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Title: 1) Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD)</p> <p>Description: Focuses on therapeutic strategies to effectively treat Chemical Warfare Agents (CWA) contamination on wounds, eyes, and large areas of intact skin. This effort involves the development of products capable of removing or neutralizing CWA from those routes of exposure, to decrease the toxic load of agent and allow optimal effectiveness of other systemic therapeutics.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue advanced preclinical studies to validate safety and efficacy in support of clinical trials. - Continue assessment of candidate products for advanced development. - Refine pathway to regulatory approval and licensure. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$6.679 Million) remains in TM2.</p>	-	-	6.351
<p>Title: 2) Enabling Science</p>	-	-	13.134

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
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Description: Focuses on protection of the Warfighter against CWA to maintain force lethality, leverage innovative approaches and emerging technologies to support modernization of chemical medical countermeasure (cMCM) pipeline, and develop and deploy cMCMs more rapidly to the Warfighter. Efforts include: 1) development of Artificial Intelligence/Machine Learning (AI/ML) tools to more efficiently identify cMCMs and assess their safety and efficacy for regulatory submission; 2) AI/ultra-high throughput screening-based sampling of large chemical spaces with the aim of providing broad spectrum cMCMs with improved efficacy and selectivity, minimal toxicity, and decreased expense and fielding times to the warfighter; 3) development of technologies to deliver MCMs across the blood brain barrier (BBB) into the brain; 4) maturation of cMCMs with innovative mechanisms of actions; and 5) development of well characterized or FDA qualified animal models, as needed, to support cMCM discovery and development under the FDA animal rule.

- FY 2023 Plans:**
- Continue to employ AI/ML-based tools for drug design and predictive drug safety.
 - Continue to maintain screening and safety databases for drug candidates
 - Continue to perform select animal and safety studies for lead therapeutic candidates, including anticholinergics, for treatment of CWAs.
 - Continue to investigate technologies for delivering therapeutics (e.g. 2-pyridine aldoxime methyl chloride/2-PAM) to the brain.
 - Continue to support the therapeutic candidate pipeline.
 - Develop well characterized or FDA qualified animal models to support the development of MCMs requiring licensure under the FDA animal rule that provide protection for the Warfighter against CWAs.
 - Continue to test the safety and efficacy of candidate resurrectors of aged/inhibited enzyme in animal models.
 - Develop naturally derived MCM with innovative mechanism of action against broad spectrum of organophosphorus nerve agent (OPNA) threats.

FY 2022 to FY 2023 Increase/Decrease Statement:
Funding transferred from another Project due to budget restructure. FY22 funding (\$11.148 Million) remains in TM2. Increase due to change in technical parameters.

Title: 3) Pharmaceutical Based Agents (PBAs)	-	-	5.586
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Description: Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to PBA. This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for FDA licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to assess drug products for use against other priority PBA emerging threats (e.g., non-opioids). <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$7.390 Million) remains in TM2. Decrease due to change in technical parameters.</p>				
<p>Title: 4) Reactivators of AChE as Therapeutics (ReACT)</p> <p>Description: The Warfighter requires rapid acting MCM to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation. Efforts in this area are designed to develop potential candidates that will ultimately be submitted for FDA licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to down select generated chemical libraries to the most promising broad spectrum therapeutic candidates for follow on safety and efficacy assessments. - Continue drug formulation efforts for MCMs with a longer shelf-life and with feasibility of an auto-injector containing material and chemical composition. - Continue development screening for novel broad spectrum enzyme reactivators that are effective in the brain. - Transition critical in vivo data to advanced developer for lead reactivators. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$5.262 Million) remains in TM2. Decrease due to change in technical parameters.</p>		-	-	4.279
<p>Title: 5) Enhanced Survivability Coatings</p> <p>Description: Efforts seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to characterize bio-inspired surface treatments for equipment coatings to repel agents of interest from current military equipment coatings. 		-	-	1.071

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record.</p> <p>- Advance thin repellent film coating systems from fundamental research to applied research test and evaluation.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB2.</p>				
<p>Title: 6) Equipment Decontamination</p> <p>Description: The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Transition methodology for testing for effective decontamination of complex surfaces and real-world systems to the Service Equipment Decontamination System or Tactical Contamination Mitigation System programs of record. - Finish development and demonstration of an autonomous decontamination platform to reduce troop-to-task burden of operational decontamination. - Develop bioagent disclosure spray and bio contamination mapping technologies into prototypes to demonstrate. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$3.150 Million) remains in CB2.</p>		-	-	5.774
<p>Title: 7) Multifunctional Materials for Protection</p> <p>Description: Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants and coatings.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop and characterize novel reactive/catalytic materials that decontaminate biological and chemical threats and integrate materials into next generation decontaminants and coatings. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	1.823

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding remains in CB2.			
<p>Title: 8) Personnel Decontamination</p> <p>Description: Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a CWA exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop and use laboratory and animal models to assess physical removal technologies for potential replacement of reactive skin decontamination lotion (RSDL). - Continue to integrate new dry decontamination into a mitt form factor and determine science and technology challenges within process and procedure improvements. This includes investigation of FDA requirements for approval of technology as a medical device. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$1.180 Million) remains in CB2. Decrease due to change in program/project schedule. Decrease due to advancement of program/project research from BA2 to BA3.</p>	-	-	0.692
<p>Title: 9) Biological Warfare Defense Therapeutics</p> <p>Description: This effort funds biomedical research focused on the early discovery and evaluation of therapeutic countermeasures against known and emerging biological warfare (BW) threats for which FDA-approved therapeutics are limited or lacking. BW defense therapeutics mitigate and reverse the effects of known and emerging biological warfare threats in symptomatic warfighters diagnosed with BW disease. They are the last line of defense against BW threats and are critical to returning symptomatic Warfighters to service. Biomedical research is focused on discovery and development of broad-spectrum therapeutic candidates and therapeutic platforms that target viruses, bacteria or toxins directly, enhance the host response (e.g., by modulating the immune system) and/or relieve BW disease symptoms. Broad-spectrum therapeutic candidates that are shown to be both safe and efficacious against BW threats in small animal models will advance for additional pre-clinical evaluation, and can be accelerated for use against emerging infectious diseases during an outbreak. Therapeutic target identification discovery and evaluation of novel small molecules (chemically synthesized), novel biologic molecules (isolated from natural sources), drug and drug/vaccine combinations (aka layered defense), and repurposing of drugs approved by the FDA for other indications, are included in this research. Development of appropriate animal models and assays in which to evaluate therapeutic candidates is also included. Projects leverage interagency and commercial sector investments to accelerate development and reduce costs.</p> <p>FY 2023 Plans:</p>	-	-	31.701

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Viral Therapeutics:</p> <ul style="list-style-type: none"> - Evaluate conserved targets, including host targets and processes of pathogenesis, for broad-spectrum treatment. - Continue drug discovery and development efforts to prepare for emerging threats by focusing on broad spectrum mechanism of action conserved targets and platform technologies. Upon establishment of proof of concept in small animal models, transition therapeutic candidates to advanced technology development. <p>Bacterial Therapeutics:</p> <ul style="list-style-type: none"> - Evaluate conserved therapeutic targets, with a focus on circumventing or overcoming antimicrobial resistance, for broad-spectrum treatment. - Continue to discover therapeutic candidates that employ novel strategies and mechanisms, such as new pathogen targets, drug delivery methods, or modulating the immune response, to overcome current and emerging mechanisms of antibiotic resistance in bacterial infections. Upon establishment of proof of concept in small animal models, transition to advanced technology development. - Establish proof of concept efficacy of biologics to treat intracellular bacterial biothreat infections to lay the groundwork for future expansion of investments in biologic therapeutic class. <p>Toxin Therapeutics:</p> <ul style="list-style-type: none"> - Continue evaluation of repurposed small molecule drug for efficacy in the treatment of multiple serotypes of botulinum neurotoxin (BoNT) in small animal models; evaluate repurposed drug in combination with botulinum antitoxin in small animal models. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in TM2.</p>				
<p>Title: 10) Discovery of Medical Countermeasures Against New and Emerging (DOMANE)</p> <p>Description: Develop and successfully transition emerging technology platforms to identify MCM, targets, as well as innovative platforms that will support transition to applied programs for clinical trials. These developmental and translational studies will provide a knowledge foundation and broad candidate pipeline that will underpin the availability (via FDA-regulated Expanded Access, Compassionate Use and Emergency Use authorities) of BW MCM to the Joint Force at the speed of relevance to allow freedom of action.</p> <p>FY 2023 Plans:</p>		-	-	5.000

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
- Pursuing high-throughput 3D structural biology, combined with organs-on-a-chip and AI/ML technologies to transition to applied programs to address mechanisms of action, drug development platforms and medical countermeasure identification			
<i>FY 2022 to FY 2023 Increase/Decrease Statement:</i> Funding transferred from another Project due to budget restructure.			
Accomplishments/Planned Programs Subtotals	-	-	75.411

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• MT3: Mitigate (ATD)	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
PT2: <i>Protect (Applied Research)</i>	-	0.000	0.000	58.758	-	58.758	59.338	59.855	61.517	63.612	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Protect Applied Research Project provides the Joint Force the ability to prevent the effects from exposure to chemical and biological hazards. PT2 emphasizes increasing protection capability and reducing physiological effects, preventing or reducing individual and collective exposures, applying prophylaxis to prevent or mitigate negative physiological effects, and protecting critical equipment in Chemical, Biological, Radiological, and Nuclear (CBRN) environments.

Thrust Areas included in this Project are:

- (1) Biological Warfare Defense Prophylaxis
- (2) Nerve Agent Prophylaxis/Pretreatments
- (3) Dynamic Multifunctional Materials for Second Skin
- (4) All-Hazards & Respiratory Protection
- (5) Multifunctional Materials for Protection
- (6) Air Purification Enhancements
- (7) Enhanced Survivability Coatings

Biological Warfare Defense Prophylaxis: Provides the Warfighter protection against biothreat agents through the pre-exposure administration of prophylactics against known bacterial, viral and toxin agents of interest and emerging infectious threats. Medical countermeasure (MCM) strategies against broader classes of biological agents will be pursued with emphasis on broad-spectrum protection based on mechanism of action. The manufacturing processes for platform technologies will be adapted to maximize flexibility, increase stability, shelf life, and expand storage conditions. Efforts will also be adapted to maximize delivery flexibility through modifying delivery routes, which will allow for dose and reagent sparing. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Nerve Agent Prophylaxis/Pretreatments: Obtain the first prophylactic MCMs designed to prevent severe morbidity and mortality upon exposure to nerve agents without the need for additional individual physical protective equipment.

Dynamic Multifunctional Materials for Second Skin: Unencumber the Warfighter by dynamically optimizing protective garment thermal burden and responsive technologies.

All-Hazards & Respiratory Protection: Improve chemical and biological agent protection while maintaining Warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit full spectrum respiratory protection.

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Multifunctional Materials for Protection: Discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.

Air Purification Enhancements: Optimize and extend filter life to save costs while maintaining or improving protection and improve integration of collective protection into developmental Service major combat platforms.

Enhanced Survivability Coatings: Address materiel surface ease of decontamination and resistance to chemical agent penetration. Projects will develop temporary coatings that resist chemical agent absorption and are quickly decontaminated in the field and allow the rapid regeneration of combat power.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
<p>Title: 1) Enhanced Survivability Coatings</p> <p>Description: Efforts seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military materiel to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return materiel to mission operations level.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to characterize bio-inspired surface treatments for materiel coatings to repel agents of interest from materiel surfaces. - Evaluate and incorporate new or commercially-available appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record. - Advance thin repellent film coating systems from fundamental research to applied research test and evaluation. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB2.</p>	-	-	1.178
<p>Title: 2) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter chemical warfare agents, including organophosphorus nerve agents (OPNA), using targeted and innovative science and technology efforts that will offer broad-spectrum protection, flexible route of administration, lower dose requirements, and reduced operational and logistical burden. The use of these medical countermeasures (MCM) will protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to develop catalytic enzymes for use against selected, priority non-traditional agents (NTA). - Complete expanded pre-clinical studies of lead catalytic scavengers to support future investigative new drug (IND) filing. 	-	-	4.158

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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Continue efforts to develop capability for rapid development of medical countermeasures. - Continue efforts to explore and further develop novel non-enzyme nerve agent prophylaxis. - Continue new approaches to identify pretreatment and prophylaxis against multiple classes of NTAs and emerging chemical threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$3.282 Million) remains in TM2. Increase due to change in program/project technical parameters.</p>				
<p>Title: 3) Dynamic Multifunction Materials for Second Skin</p> <p>Description: Efforts will utilize responsive technologies to provide chemical biological protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments. These technologies include interpenetrating polymer networks that will change moisture permeability and molecular selectivity on demand, and membranes with higher moisture vapor transfer rates than existing fabrics.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development and testing of protective garment materials that respond to the presence of chemical agents to increase Warfighter protection. - Begin integration of responsive systems into protective suit paradigms for whole system testing. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.839 Million) remains in CB2.</p>		-	-	1.793
<p>Title: 4) All-Hazards & Respiratory Protection</p> <p>Description: Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit full spectrum respiratory protection.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete evaluate and assess systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Transition operationally-relevant respirator fit testing system to the Joint Service Mask Leakage Tester (JSMLT). - Transition specification for anti-fog lenses in respirators as a Ground Mask modification work order. 		-	-	1.482

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) PT2 / Protect (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
- Continue to design and test prototypes for a low-encumbrance, next generation protective mask.				
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.380 Million) remains in CB2.				
Title: 5) Multifunctional Materials for Protection Description: Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents. FY 2023 Plans: - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to feed air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Advance next generation materials to design reactive, regenerative protective garments with longer service life and lower thermal burden. FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB2.		-	-	2.743
Title: 6) Air Purification Enhancements Description: Efforts focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection. FY 2023 Plans: - Continue materials testing for effectiveness against novel threats for Next Generation Filtration systems. - Complete and publish report on computational modeling for filter protection against advanced agents. - Complete and publish report on design of high air flow collective protection systems that increase the performance against advanced agents delivered in all states of matter (vapor, aerosol, and liquid) in operationally relevant environments. - Continue to engineer novel filter bed materials for chemical agent destruction, integrate them into next generation filters, and develop methods to assess filter performance in an operationally-relevant environment.		-	-	4.705

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Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) PT2 / Protect (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Develop low-cost, continuous operation collective protection engineering standards and guidelines for temp, rapid enhancement of unprotected facilities during pandemic/bio warfare attack.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$0.393 Million) remains in CB2. Increase due to change in program/project technical parameters.</p> <p>Title: 7) Biological Warfare Defense Prophylaxis</p> <p>Description: The ultimate protection of the Warfighter is achieved by pretreating the Warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the Warfighter to work in a less restrictive environment, absent of any personal protective equipment, facilitating the Warfighter to operate at peak performance. Efforts support innovative concepts in prophylaxis that support needs specific to the warfighter such as broad spectrum protection, rapid onset to protection, fewer doses required, no cold chain required, and needle-free administration.</p> <p>FY 2023 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Continue development of nanobodies. - Continue plague and melioidosis human surveillance. - Continue non-human primate (NHP) model development for co-infection models. - Continue NHP melioidosis neurological model. - Initiate development of plaque mRNA vaccine. - Continue to evaluate protective efficacy of Anthrax vaccines against novel Bacillus anthracis strains. <p>Viral:</p> <ul style="list-style-type: none"> - Conduct nonclinical studies for vaccines and pretreatments for Crimean Congo Hemorrhagic Fever viruses. - Complete Marburg virus infection studies of bats. - Continue immune correlate identification for Ebola. <p>Toxins:</p> <ul style="list-style-type: none"> - Increase half-life of monoclonal antibodies (mAb) and scale up manufacturing of mAb against marine toxins. - Continue evaluation of naturally occurring anti-toxins to protect against marine toxins. - Continue to develop novel antitoxin technologies including exploring the use of cell membrane coated nanosponges. - Continue evaluation of toxins and antitoxin prophylaxis in animal models. - Continue to develop functional assays to determine biological activity for various toxins. 		-	-	26.699

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program **Date:** April 2022

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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Broad Spectrum:</p> <ul style="list-style-type: none"> - Continue novel pan virus nanosponge platform development and animal testing to address emerging threats, explore additional applications of nanosponge technology to include emerging toxin and bacterial threats. - Continue development of a prototype broad spectrum neuronal nanosponge platform technology. - Continue exploration of additional strategies and platforms for broad spectrum protection to address protection against emerging threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$29.560 Million) remains in TM2. Decrease due to change in program/project technical parameters.</p>			
<p>Title: 8) Biological Warfare Defense Prophylaxis - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Innate Immune Training and Adjuvant Discovery & Tissue Targeting of Vaccines to Enhance Immune Response. Investments include efforts to strengthen and tune the host immune system through enhancement or stimulation to increase the ability to resist disease progression and spread. Characterization of vaccine platform technologies relative to the way a pathogen or toxin causes disease and how the host immune system responds will be executed to optimize matching of a disease indication with the most appropriate vaccine platform.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Develop a predictive capability to rapidly identify the optimal vaccine platform with which to counter any particular current, novel or emerging biological threat. - Initiation of projects that identify and evaluate adjuvants/encapsulation formulations/mucosal delivery technologies that can be combined with vaccines to stimulate a customized immunogenicity profile without compromising vaccine safety. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>	-	-	16.000
Accomplishments/Planned Programs Subtotals	-	-	58.758

C. Other Program Funding Summary (\$ in Millions)											
<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• PT3: Protect (ATD)	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing

Remarks

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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D. Acquisition Strategy
N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
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COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
UN2: <i>Understand (Applied Research)</i>	-	0.000	0.000	122.028	-	122.028	117.683	105.509	101.577	100.929	Continuing	Continuing

A. Mission Description and Budget Item Justification

The Understand Applied Research Project provides the Joint Force the ability to detection, identification and characterization of chemical and biological (CB) threat agents and decision support. This includes classification and/or identification of the threat and potentially the amount of CBRN hazards in all physical states. Efforts provide the ability to characterize the chemical, biological, radiological, and nuclear (CBRN) hazard to a commander and develop a clear understanding of the current and predicted CBRN situation; collect, query, and assimilate information from sensors, intelligence and medical communities, etc., in near real time to inform decisions; and provide actual and potential impacts of CBRN hazards.

Thrust Areas included in this Project are:

- (1) CBRN Battlespace Surveillance, Alerting & Response
- (2) CBRN Decision Aids
- (3) CBRN Situational Awareness
- (4) Employment Characterization
- (5) Environmental Response
- (6) First Look
- (7) Host Response
- (8) Technical Surprise
- (9) Unattended Perimeter Monitoring
- (10) Unconventional Detection Modalities
- (11) Distributed CB Reconnaissance
- (12) Expeditionary Analytical Toolkit (ExAnT)
- (13) Chemical Diagnostics
- (14) Diagnostic Building Blocks
- (15) Emerging Threats

CBRN Battlespace Surveillance, Alerting & Response: Development of algorithms that generate and disseminate warning to personnel in time to prevent exposure to or limit the impact of CBRN threats. This thrust area conducts data collection trials to support algorithm development; leverage Artificial Intelligence (AI) to identify key indicators, combinations of indicators, and sensing modalities to reduce false alarms and predict the likelihood of exposure; explore remote and contactless monitoring and analysis for application in Warfighter chemical and biological threat exposure alerting.

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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<p>CBRN Decision Aids: Providing tools that assess risk from CBRN hazards and identify courses of action to limit impact. This thrust area permits connectivity, enabling the dynamic discovery, querying, and control of sensors through standard protocols; allow for dynamic discovery and integration between networked devices at the tactical edge to enable sharing of information and capabilities across connected components.</p> <p>CBRN Situational Awareness: Providing operationally relevant context to CB-specific phenomena data to ensure the Joint Force is able to characterize new CB hazards and mitigate their effects on mission success. This thrust area provides the analytic framework to determine optimal defense postures by extrapolating scientific data generated during the course of technology development and hazard assessment data into an assessment to help inform operational utility.</p> <p>Employment Characterization: Studies to help refine threat assessments and potential impacts of indoor or outdoor releases of threat agents on operations, strategy, and capabilities. This area includes both laboratory chamber-based dissemination characterization, as well as full-scale outdoor trials. Results from studies help determine risks posed by an agent employed in a similar fashion by an adversary.</p> <p>Environmental Response: Efforts to evaluate CB threats that have been released into the environment (e.g. persistence, degradation, and decomposition), along with the affects environmental conditions (e.g. ozone, ultraviolet, humidity, etc.) have on those agents. These efforts identify and characterize agent behavior of chemical and biological agents in the environment (including soil, water, and plants), in clothing, on and in structures, and on equipment to support model development and decision-making tools.</p> <p>First Look: Provides the initial characterization of potential CB threats, and provides a fundamental assessment of the potential risk they pose. Investments in this area evaluate agents as well as develop methods and capabilities to quickly and accurately characterize chemical, biological, and toxin agent properties to inform capability development, modeling, CB defense community stakeholders.</p> <p>Host Response: Characterizes effects (acute vs. chronic) from exposure to toxic chemical or infectious biological agents using operationally relevant exposure scenarios, exposure routes and appropriate assessment methods and models. All of these are used to improve the understanding of mechanisms of action, infectivity, morbidity, and mortality of agents, and provide adverse health effects information and other relevant data. Data from host response studies are also used to help develop predictive capabilities for capturing the human response to chemical and biological threat agents. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.</p> <p>Technical Surprise: Mitigate surprise by providing technology watch and horizon scanning tools to assess advances in technologies and scientific knowledge, with focus on breakthroughs that overcome bottlenecks and enable development of capabilities of concern. Efforts in this area improve threat awareness scanning capabilities to allow for continuous, real-time monitoring for identifying emerging threats, maintain situational awareness of the threat environment, and assess technological convergence.</p> <p>Unattended Perimeter Monitoring: Invests in efforts supporting Integrated Early Warning and Integrated Layered Defense by establishing a layered defense capability through developing and implementing automated and integrated technologies enabling unattended monitoring for biothreats.</p>		

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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Unconventional Detection Modalities: Develops disruptive technologies to identify unknown or emerging chemical threats and develops chemical sensors that can operate in complex threat environments with high fidelity. Efforts include utilizing machine learning and other advanced computational tools to increase detection and identification accuracy, reduce false alarms, and enable mapping of hazardous locations to support integrated early warning (IEW) capabilities. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Distributed CB Reconnaissance: Enhances early warning and situational awareness of CB threats while reducing potential Warfighter exposure using distributed CB reconnaissance tools to include low-cost point sensors and sensing/collection systems for unmanned platforms. Efforts include developing threat sensing and sampling payloads for manned and unmanned aerial and ground platforms to enhance early warning and situational awareness of CB threats.

Expeditionary Analytical Toolkit (ExAnT): Provides general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.

Chemical Diagnostics: Discovers innovative and integrated capabilities that are able to diagnose threats across the chemical spectrum and enhance force protection by investing in diagnostics for exposure to traditional and nontraditional Chemical Warfare Agents (CWA), including pharmaceutical based agents. Efforts include coordinating with Threat Agent Science and the Intelligence Community and to understand the chemical threat space.

Diagnostic Building Blocks: Develops foundational capabilities for the entire diagnostics portfolio; invests in innovative, cutting-edge technologies to improve the development pipeline for diagnostics; and exploits areas in artificial intelligence synthetic biology and machine learning to develop novel and rapid diagnostic tests for utilization. Efforts accelerate assay development timelines and optimize test parameters by leveraging novel concepts and tools that readily allow a pivot to assay development for emerging threats. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

Emerging Threats: Efforts to push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Investments in developing diagnostic systems that leverage novel approaches to characterize the pathogen or the host response enables the delivery of actionable information, such as administering the appropriate antibiotic, antiviral, or vaccine to a medic or primary care provider. The FY23 efforts include additional investments in enhanced biodefense and pandemic preparedness.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
<p>Title: 1) CBRN Battlespace Surveillance, Alerting & Response</p> <p>Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. Current predictive algorithms in development are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological (CB) agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures</p>	-	-	8.000

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue wearable device-based non-invasive biomarker analysis and algorithm enhancement for pre-symptomatic indication of chemical or biological exposure. - Continue to develop predictive algorithms and analytic tools utilizing artificial intelligence (AI) and ML techniques to allow for rapid response to emerging threats and detection of genetically engineered pathogens. - Continue development of AI-based drug discovery algorithms for Emerging Threats. - Continue the advancement of standoff physiological monitoring capabilities. - Utilize a multi-organ chip system to characterize the effects of biological threat agents on several different cultured human tissues and conduct multi-omics analysis (e.g. proteomics, metabolomics) to identify potential biomarkers associated with physiological responses from exposure to high, mid, and low multiplicity of infection. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$9.459 Million) remains in CB2. Decrease due to change in program/project schedule and completion of the major warning algorithm development efforts for predicting altered health severity and duration.</p>				
<p>Title: 2) CBRN Decision Aids</p> <p>Description: In order to unencumber the Warfighter at the tactical edge, efforts continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards. Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development of warning and decision aids for tactical users leveraging the compute resources resident on EUDs. - Continue development of AR-based technologies to incorporate CB threat situational awareness in EUDs. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		-	-	4.667

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$3.100 Million) remains in CB2. Increase due to change in program/project technical parameters.			

<p>Title: 3) CBRN Situational Awareness</p> <p>Description: Efforts will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled. Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield. Efforts will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems to operationalize reachback support. Efforts will further enhance hazard modeling by creating a seamless indoor-to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy. Develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, efforts will leverage threat agent science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Complete development of models to provide operationally relevant outputs to support medical decision making. - Continue to develop ML algorithms for disease prediction and forecasting for mobile platforms. - Continue to enhance CB situational awareness capabilities for integration into Heads up Display (HUD) technologies. - Initiate efforts to expand focus on emerging threat hazard modeling, leveraging TAS data to ensure the Joint Force is able to characterize new CB hazards and mitigate their effects on mission success. - Explore new areas for targeted investment in synthetic environments to provide a CBRN-specific cognitive, collective, multi-echelon training and mission readiness capability. - Explore in-host modeling capabilities leveraging ML/AI techniques to characterize predictive biomarkers of chemical and biological exposure prior to onset of symptoms. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	-	-	11.812
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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$10.894 Million) remains in CB2.				
<p>Title: 4) Employment Characterization</p> <p>Description: Employment Characterization studies refine threat assessments and identify potential impacts of indoor and/or outdoor releases of threat agents on CBDP operations, strategy, and capabilities. These studies directly define the Warfighter threat space by determining how CB agents behave when released. This effort reduces risk to the CBDP Enterprise by closing knowledge gaps and informing on the type, extent and magnitude of a potential hazard a warfighter may face in an operational environment. Employment Characterization will: review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and TAS assessment opportunities; continue coordination with international partners to leverage skills and resources; develop closer linkages to hazard prediction modelers to identify knowledge gaps and TAS opportunities; prepare evaluation of potential munitions for applicability to potential future threats based on performance characteristics; and continue chamber tests and operational trials as appropriate for compounds of interest.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and threat agent science assessment opportunities. - Continue studying scale employment methods and feasibility for emerging threat agents. - Begin Toxin Dissemination Efficiency and Anti-Material Efficacy Characterization studies. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred from another Project due to budget restructure. FY22 funding (\$4.159 Million) remains in TM2.</p>		-	-	4.657
<p>Title: 5) Environmental Response</p> <p>Description: Environmental Response evaluates CB threats to understand how they will behave in the environment (e.g. persistence, degradation, decomposition), along with the effects of environmental conditions (e.g. ozone, ultraviolet, humidity, etc.) on those agents. Studies include evaluations of CB threat agents on soil, water, and plants, and operational surfaces such as clothing, structures, and equipment. This thrust area reduces risk to the CBDP Enterprise by closing knowledge gaps and informing on the type, extent and magnitude of a potential hazard a warfighter may face in an operational environment. Small-scale laboratory measurements are used to predict the larger-scale behavior and fate of the agents in outdoor and operational settings, while examining agents deposited on operationally relevant substrates refines our understanding of their environmental persistence and hazards. Knowledge obtained from Environmental Response is used to inform operators, predictive model development, and capability development.</p> <p>FY 2023 Plans:</p>		-	-	6.042

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Continue evaluating stability of toxin and viral threats, including exploring the fundamental characteristics that influence viral stability in the environment. - Continue closing knowledge gaps associated with aerosol biology and its implications with the outdoor release of biological threats. - Continue environmental characterization of chemical threats, increasing evaluation of degradation products and reaction byproducts for detection, diagnostics and other applications. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$5.548 Million) remains in CB2. Increase due to change in program/project technical parameters.</p>				
<p>Title: 6) First Look (Chemical and Biological)</p> <p>Description: First Look provides the initial evaluation of known and emerging threat agents to determine their potential hazard to the Warfighter. For both chemical and biological agents, this initial fundamental risk assessment includes evaluation of synthesis and toxicity screening for chemicals and toxins and growth and/or virulence for biological agents as well as production and feasibility of weaponization for all agents. Investments in this area are used to evaluate threat agents as well as develop methods and capabilities to quickly and accurately characterize chemical, biological, and toxin threat agent properties. First Look products/data inform warfighter mission planning, requirements generation, capability development, model development, the larger CBDP Enterprise, Intelligence and other government stakeholders about known or emerging agent threats.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue developing innovative laboratory tools and approaches to enable expedient characterization of emerging or novel biological threats (to include highly infectious and novel organisms), including understanding enabling technologies' impact to gene modification/expression and the ability to assess toxin activity. - Continue developing advanced methods for threat agent characterization, including more complex chemical agent mixtures or combinations. - Continue evaluating findings of technological advancement implications to discounted threats study. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$9.850 Million) remains in CB2.</p>		-	-	9.850
<p>Title: 7) Host Response</p> <p>Description: Host Response assesses the human response of exposure to CB threat agents using operationally relevant exposure scenarios (acute versus chronic) and exposure routes (e.g., inhalation, dermal, ingestion, etc.) and appropriate assessment methods and models. Data from host response studies are used to develop quantitative exposure limits and</p>		-	-	14.453

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>qualitative information (e.g. mechanism of action) to inform Warfighter mission planning, requirements generation, capability development, model development, the larger CBDP Enterprise, Intelligence and other government stakeholders. Include predictive capabilities for rapidly assessing the human response to chemical and biological threat agents. In addition, host response will be working to close known knowledge gaps associated with traditional threats, including exploring synergistic effects associated with combinatorial agent exposures. Bioavailability of threats that are encapsulated to understand host response differences between exposures to encapsulated versus un-encapsulated threats will be also be assessed.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to build on and develop predictive methods and technologies for CB agent characterizations. - Continue studies to address host response areas identified by the FY21 gap analysis study for traditional biological agents. - Deliver IOC (initial operating capacity) for CRISTAL (Computational Rapid Identification and Scientific Threat Analysis) incorporating results into future host response. Continue to enhance and modernize CRISTAL methods and tools. - Continue to assess the human (host) response to novel and emerging threats (including combinatorial and mixtures). <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$15.200 Million) remains in CB2. Decrease due to change in program/project technical parameters.</p>				
<p>Title: 8) Host Response - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Advanced Pathogen and Emerging Threat Characterization with attention on characterizing host responses and pathogen signatures using multi-omic analyses and enabling technologies to develop the ability to characterize known and emerging threats. This effort will include understanding the host response to various pathogen insults to identify patterns of response that allow for the prediction of novel threat agents based on the host responses they generate. Evaluations of pathogenesis and viral transmission to understand differences in disease severity will also be conducted. Within this program, efforts to characterize synthetic and natural viral pathogens to compare varying gene expressions between the two will be executed. This program accelerates the ability to characterize emerging threats and will generate more robust data sets for training threat agnostic tools to provide better characterization capabilities.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Begin the development of a robust characterization pipeline capable of characterizing emerging pathogens. - Begin the development of robust threat agnostic tools to characterize emerging pathogens. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	3.000
<p>Title: 9) Technical Surprise</p>		-	-	4.500

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>Description: Technical Surprise assesses technological advancements for potential implications to the threat space, including agent use and release. Technical Surprise includes horizon scanning to identify potential areas of concern as well as conducts technical assessments of emerging technological advancements (e.g. biotechnology, artificial intelligence, machine learning, quantum computing). This program develops capabilities to evaluate and assess technical enhancements that may alter the nature or magnitude of a threat agent. The technical surprise program will be evaluating emerging technologies and convergence of technologies that improve the ease of threat use and make threats more likely to survive being released. Identify the limitations and barriers associated with synthetic biology and assess the implications. These efforts will identify and assess former technology hurdles that have been lowered or overcome and assess implications of increasing potential threat.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue identifying and assessing technological advancements that will impact the chemical and biological threat space, including potential threats that are not specifically chemical or biological in nature, but have implications to chemical and biological defense capabilities. - Continue a horizon scanning capability to provide situational awareness in assessing technological growth and convergence that can affect the chemical and biological threat space, while keeping abreast of changes in the nature of future threats. - Continue the assessment of synthetic biological tools and other biotechnology developments that can enhance or alter the threat space. - Enhance evaluation of converging technologies and their implications to the threat space. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.500 Million) remains in CB2.</p>			
<p>Title: 10) Unattended Perimeter Monitoring</p> <p>Description: Develop automated technologies to improve detection of aerosolized hazards while minimizing or removing user intervention to enable a reliable detect-to-warn capability, providing a capability for unattended monitoring of perimeters for temporary defense positioning, including base camps, to enable early indication of threats. This thrust area will evaluate current and novel technologies to provide improved chemical threat detection and automated biological detection capabilities.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to evaluate the use of computational tools, like machine learning, into detector/identifier technologies to further reduce false reporting due to environmental factors. - Continue to make technological improvements to enhance early warning of aerosolized biological threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	-	-	4.871

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred from another Project due to budget restructure. FY22 funding (\$4.114 Million) remains in CB2. Decrease due to division of Unattended Perimeter Monitoring between Chemical and Biological efforts.				
<p>Title: 11) Unconventional Detection Modalities</p> <p>Description: This effort will focus on Biodetection Screening. Develop disruptive technologies to identify unknown or emerging threats and develop sensors that can operate in complex threat environments with high fidelity. This thrust area supports others as appropriate to the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue refinement of novel optical detector for bioaerosols modernizing current technologies. - Explore innovative detection methods such as synthetic or organ on a chip biosensors to provide agent agnostic techniques that identify an unknown as hazardous to a human. - Continue to integrate advanced computational tools, Artificial Intelligence (AI)/Machine Learning (ML) into sensor development to improve speed of detection, reduce false alarms and enable integration of data from multiple detection sources. - Initiate Assays on-Demand efforts aimed to rapidly deliver novel assay solutions to be used in the field. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.997 Million) remains in CB2.</p>		-	-	6.681
<p>Title: 12) Unconventional Detection Modalities - Enhanced Biodefense (ENBD)</p> <p>Description: Develop disruptive technologies to identify unknown or emerging threats and develop sensors that can operate in complex threat environments with high fidelity. This thrust area supports others as appropriate to the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Expand Assays on Demand (AoD) for emerging biological threat detection. AoD will allow for real time assay manufacturing reducing supply chain constraints typically seen in currently fielded systems. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	2.000
<p>Title: 13) Distributed CB Reconnaissance</p> <p>Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will</p>		-	-	3.614

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/ collection systems that are rugged, rapid and accurate.				
<p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to invest in low size, weight, power, and cost technologies for near-real time detection capabilities for deployable or distributed biological and chemical sensing for hazard awareness and assessment of operational environments. - Invest in innovative technologies to increase situational awareness using manned and unmanned platforms and provide operational advantages to the Warfighter. - Explore application of advanced computational tools, Artificial Intelligence (AI) and Machine Learning (ML), to connect multiple sensor technologies to provide improved early warning and integrated threat awareness <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding remains in CB2.</p>				
<p>Title: 14) Enhanced/Emerging Biothreat Sensing</p> <p>Description: Establish a capability to rapidly develop advanced, agile, pathogen-agnostic laboratory and field forward detection capabilities to detect emerging and enhanced biological threats across all force echelons (presumptive, field confirmatory, theater validation, and definitive identification). Further, multi-omics and data sciences (MODS) - multiple biological measurements - will be used to modernize laboratory capabilities and leverage synthetic biology methods and tools to deliver enhanced biothreat sensing/detection capabilities to the Joint Force.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue development of detection algorithms and laboratory workflows to identify threats in unknown samples. - Continue automated computational tools to design and expedite assay development for biological detection. - Complete applied research component of far-forward pathogen agnostic sensing toolkit development. - Incorporate advanced biological measurements and data processing techniques into sensor development to enable an agile response to emerging threats with emerging pathogen targeted detection capabilities. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$9.825 Million) remains in CB2. Increase due to accelerated development effort.</p>		-	-	12.853
<p>Title: 15) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p>		-	-	3.596

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue to support expeditionary forces in leveraging reach-back capabilities for identification purposes. Invest in novel detection capabilities to address opioids and emerging chemical threats. - Continue to invest in improvements of current detection technologies for chemical hazards in complex and obscurant-heavy environments. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$3.333 Million) remains in CB2.</p>			
<p>Title: 16) Chemical Diagnostics</p> <p>Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional Chemical Warfare Agents (CWAs), including pharmaceutical based agents (PBAs). Leverage the development of a chemical diagnostic that monitors blood, indicating whether a Warfighter has been exposed to nerve agents within minutes.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Continue the development of integrated capabilities that address portable ultra-low detection of opioids to the ChemDx device that will allow for differentiating between classes of CWAs, resulting in more informed treatment decisions. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$1.554 Million) remains in TM2. Decrease due to change in technical parameter.</p>	-	-	0.693
<p>Title: 17) Diagnostic Building Blocks</p> <p>Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats and speed up development to days instead of weeks.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Initiate field validation studies for diagnostics prototypes using synthetic binders and evaluate performance against current gold standard diagnostic methods. 	-	-	3.466

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue efforts to collect the baseline data required for future development of a whole breath diagnostic platform the use of breath as a non-invasive sampling mechanism offers Warfighters little-to-no interruption to mission activities and provides the opportunity for earlier diagnosis/indication of infection or chemical exposure.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.446 Million) remains in TM2. Decrease due to change in technical parameter.</p>				
<p>Title: 18) Diagnostic Building Blocks - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Assay Development and Delivery Pipeline, Expand Biological Artificial Intelligence for Diagnostics (BioAID) Efforts as well as developing novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats and speed up development to days instead of weeks.</p> <p>FY 2023 Plans: - Expand work with collection & analysis of individual's breath, skin emissions or other minimally invasive testing methods which offers Warfighters little-to-no interruption to mission activities and provides the opportunity for earlier diagnosis/indication of infection or chemical exposure.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	6.500
<p>Title: 19) Emerging Threats</p> <p>Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.</p> <p>FY 2023 Plans: - Complete efforts on several complementary approaches to address challenges in small molecule toxin diagnosis at the POC and initiate validation of these prototypes for potential use as a threat agnostic capability to enable field-forward responses to emerging threats.</p>		-	-	2.773

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022			
Appropriation/Budget Activity 0400 / 2		R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023	
<p>- Complete the development of a universal blood sample preparation platform to be compatible with several diagnostic systems, improving the speed of sample preparation tools at low pathogen concentrations (i.e. pre-symptomatic levels) is one of the biggest challenges holding back diagnostics in point-of-care, outbreak, and remote testing scenarios.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred from another Project due to budget restructure. FY22 funding (\$4.110 Million) remains in TM2. Decrease due to change in technical parameter.</p>					
<p>Title: 20) Emerging Threats - Enhanced Biodefense (ENBD)</p> <p>Description: This effort will focus on Novel Non-Invasive Screening and Characterization. It will push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.</p> <p>FY 2023 Plans:</p> <ul style="list-style-type: none"> - Investing in training and development efforts by the Army Medical Research Institute for Infectious Disease (USAMRIID) to become an authorized developer of assays for the Cepheid Flex Cart technology (ISO MPDS). - Initiate efforts to explore innovative methods to investigate genetically modified threats including pre-symptomatic, host-based biomarkers or synthetic biology approaches. Novel methods will allow for rapid assay fielding potentially cutting development time from months to weeks. - Accelerate next generation diagnostic platform development to meet the evolving needs of the CBDP enterprise, providing diagnostics that would address detection and identification technology needs with a combined affinity based and molecular platform for emerging pathogens. - Initiate effort to predict disease severity to provide agnostic disease screening tool that enhances triage, transport and resource decision making support for the Warfighter in field forward environments. - Expand agnostic biomimetic sensing to explore additional panels of small and large molecular weight toxins with various modes of activity, and tested in both clinical and aerosol sample matrices to include environmental background. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Additional investment in enhanced biodefense and pandemic preparedness.</p>		-	-	8.000	
Accomplishments/Planned Programs Subtotals		-	-	122.028	

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) UN2 / Understand (Applied Research)
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• UN3: Understand (ATD)	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 2					R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
CB2: Chemical Biological Defense (Applied Research)	-	95.517	104.362	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	199.879

A. Mission Description and Budget Item Justification

Project CB2 provides physical science applied research to develop future, multi-disciplinary, and multi-functional capabilities in life sciences, physical sciences, environmental sciences, mathematics, cognitive sciences, and engineering. Efforts in this project support the seamless integration of state-of-the-art-technologies into a collection of systems across the spectrum of capabilities required to support chemical and biological defense missions. In FY2023, the CBDP RDT&E Projects have been restructured to align to the CBDP portfolio. CB2 thrust areas in FY2022 progress to the Mitigate (MT2), Protect (PT2), and Understand (UN2) portfolios. This restructuring is intended to provide standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

- Protection and hazard mitigation focuses on providing technologies that protect from and reduce the impact of chemical/biological threat or hazard to the Warfighter, weapons platforms, and structures.
- Detection focuses on developing technologies for remote and point detection and identification of chemical and biological agents.
- Decision analysis and management focuses on advanced hazard prediction, medical and epidemiological modeling of biological agents, operational effects and risk assessment, and systems performance modeling.
- Warning and reporting focuses on methods of alerting to chemical or biological threat agent releases and exposures.
- Threat agent science is devoted to characterizing threat agents and the hazards they present in terms of agent fate in the environment, toxicology, and pathogenicity, and focuses on the horizontal integration of threat agent information across CB defensive technologies in support of the Joint Services.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Distributed CB Reconnaissance	3.525	3.328	-
Description: Develop threat sensing and sampling payloads for manned and unmanned aerial system (UAS) and ground (UGS) platforms to enhance early warning and situational awareness of biological and chemical threats. Sensor development will support dismounted reconnaissance and surveillance missions by providing low size, weight, power and cost sensors or sensing/collection systems that are rugged, rapid and accurate.			
FY 2022 Plans:			
- Evaluate low size, weight, power, and cost technologies for near-real time detection capabilities for deployable or distributed biological and chemical sensing for hazard awareness and assessment of operational environments.			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Identify innovative solutions to increase situational awareness using manned and unmanned platforms and provide operational advantages to the Warfighter.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.614 Million) transferred to UN2.</p>				
<p>Title: 2) Enhanced/Emerging Biothreat Sensing</p> <p>Description: Establish a capability responsive to detecting emerging and enhanced biological threats across all force echelons (presumptive, field confirmatory, theater validation, and definitive identification) through a pathogen-agnostic laboratory workflow coupled with advanced computational tools that produce a field ready test. field forward detection capabilities to detect emerging and enhanced biological threats across all force echelons. Further, advanced biological measurement approaches and data processing sciences to understand if a biological sample presents threat characteristics that could harm the warfighter. Leveraged modern laboratory capabilities and synthetic biology methods to deliver enhance biothreat sensing capabilities to the Joint Force.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of algorithms and laboratory workflows to identify threats in unknown samples. - Continue development of far-forward pathogen agnostic sensing toolkit. - Continue automated in-silico design to expedite assay development. - Accelerate transitions of multi-omic data tools from interagency partners, leveraging increasing understanding of the fundamental biology of emerging and engineered threats to inform development of agile sensors with optimized detection targets and capabilities. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$12.853 Million) transferred to UN2.</p>		6.170	9.825	-
<p>Title: 3) Expeditionary Analytical Toolkit (ExAnT)</p> <p>Description: Provide general and specialized forces with the ability to modernize detection technologies for traditional threats while enhancing detection capabilities for non-traditional, emerging, and mixed chemical hazards.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Support expeditionary forces in leveraging reach-back capabilities for identification purposes. - Continue to develop advance detection capabilities to detect chemical warfare agents in complex and obscurant-heavy environments. - Evaluate detectors ability to measure hazards in complex environments and samples. - Advance detection capabilities by developing sensor platforms for integration into a portable device. 		2.502	3.333	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Anticipate future detection capability needs to support the warfighter in CB-contested operational environments. - Evaluate and transition compact vapor detectors for the Warfighter. - Continue to develop novel data processing and data analysis algorithms based on machine learning techniques. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.596 Million) transferred to UN2.</p>				
<p>Title: 4) Unattended Perimeter Monitoring</p> <p>Description: Develop automated technologies to improve detection of aerosolized hazards while minimizing or removing user intervention to enable a reliable detect-to-warn capability, providing a capability for unattended monitoring of perimeters for temporary defense positioning, including base camps, to enable early indication of threats. This thrust area will evaluate current and novel technologies to provide improved chemical threat detection and automated biological detection capabilities.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Evaluate the use of machine learning into detector/identifier technologies to further reduce false reporting due to environmental factors. - Continue development of fully-automated biosurveillance system capable of air sample collection, sample preparation, and analysis. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.871 Million) transferred to UN2.</p>		2.130	4.114	-
<p>Title: 5) Unconventional Detection Modalities</p> <p>Description: Develop disruptive technologies to identify unknown or emerging threats and develop sensors that can operate in complex threat environments with high fidelity. This thrust area supports others as appropriate to the Joint Force mission needs (e.g., expeditionary, perimeter defense, or unmanned reconnaissance).</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Conduct detection sensing validation for detection by utilizing nanoparticles and voltammetry electrochemistry. - Conduct model testing and validation of machine learning algorithms for chemical detection sensors. - Miniaturize and refine optical light scattering prototype. - Conduct live-agent testing using cell-free platforms. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$6.681 Million) transferred to UN2.</p>		6.282	4.997	-
<p>Title: 6) Enhanced Survivability Coatings</p>		2.874	2.436	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Description: This effort supports the Materiel Contamination Mitigation. Military equipment coatings are challenging and logistically intensive to decontaminate. Efforts within this thrust seek to produce enhanced coatings that increase chemical warfare agent survivability and decontaminability of military equipment to levels comparable to that of stainless steel. Improved coatings will resist chemical agent absorption and be quickly decontaminated in field, to rapidly return equipment to mission operations level.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Improve success of decontamination through the evaluation and incorporation of appliques (to include chemical transport studies in current military coatings, novel coatings characterization, thin film overcoats, strippable coat, reactive coat, and lock-down coats) in support of CBRN Coatings, Coverings, and Protective Overlays Program of Record. - Incorporate bio-inspired surface treatments for equipment coatings to repel agents of interest from current military equipment coatings. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding transferred to MT2 (\$1.071)and PT2 (\$1.178).</p>				
<p>Title: 7) Equipment Decontamination</p> <p>Description: This effort supports the Materiel Contamination Mitigation. The Warfighter has a limited capability to decontaminate personal equipment, weapons, vehicles, ships, and facilities; Sensitive equipment (weapon system optics, electronic equipment, interior spaces, and aircraft); and hazardous waste. Efforts within this thrust seek to develop decontaminant formulations and procedures that reduce or eliminate residual contamination hazards; enable unit-level decontamination with rapid unmasking; reduce logistic needs (need for water); enable rapid sorting of clean from dirty to rapidly return high-value equipment to normal use; and develop improved realistic test methods.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Begin integrating contamination mitigation technologies by advancing the proof of concept for hot-air CWA decontamination by validating the operational performance envelope. Successful efforts will result in improved efficacy, materials compatibility, flexibility, and reduced logistical burden compared to existing and emerging decontamination program requirements. - Transition Sprayable Decontaminant Slurry technology for immediate chemical warfare agent decontamination of equipment to the Service Equipment Decontamination System (SEDS). <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$5.774 Million) transferred to MT2.</p>		1.866	3.150	-
<p>Title: 8) Wide Area Decontamination</p>		0.778	-	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Description: This effort supports the Materiel Contamination Mitigation Core Capability Area. Warfighters lack capability to rapidly restore critical DoD infrastructure (e.g., sea port or air base) that will mitigate contamination spread and enable normal, unprotected operations. Efforts within this thrust seek to improve contamination mitigation logistics/cost reduction, effectiveness, compatibility/safety, and environmental compatibility.</p>				
<p>Title: 9) CBRN Battlespace Surveillance, Alerting & Response</p> <p>Description: Improve the Department of Defense's capability to detect, identify, alert, and responds to deliberate releases and naturally occurring outbreaks of chemical and biological threat agents. Current predictive algorithms in development by JSTO are based on large in-hospital datasets from patients with comorbidities. Improving on the applicability and efficacy of these algorithms will focus on large, real-time human data collects of chemical and biological agent / agent proxy exposures. Additionally, studies will focus on examining the feasibility of specifically isolating indicators of respiratory infection, determining severity of infection, and predicting return to mission readiness after exposure. This capability will enable early implementation of countermeasures such as isolation, quarantine, and removal from an area, thus potentially reducing transmission, morbidity, and mortality rates. The maturation of algorithms will incorporate Machine Learning (ML) approaches for refining sensitivity and specificity.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to expand wearable device-based non-invasive biomarker analysis for pre-symptomatic indication of chemical or biological exposure. - Complete early warning algorithm development for predicting altered health severity and duration to inform warfighter time-to mission-readiness. - Continue to develop ML algorithms to detect signatures of genetically engineered pathogens. - Continue to develop predictive algorithms and analytic tools utilizing Artificial Intelligence (AI) and ML techniques to allow for rapid response to Emerging Threats. - Initiate the development of AI based drug discovery algorithms for Emerging Threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$8.000 Million) transferred to UN2.</p>		8.064	9.459	-
<p>Title: 10) CBRN Decision Aids</p> <p>Description: In order to unencumber the warfighter at the tactical edge, JSTO will continue to develop and field CBRN Decision Aids on End User Devices (EUDs) in both connected and disconnected operations. Capabilities will focus on utilizing automation, reducing the burden experienced by the warfighter, while providing accurate, actionable information. During this time period, a</p>		4.603	3.100	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>focus will be put on developing a Contamination Avoidance Decision Aid to inform the warfighter on how to avoid, respond to and plan routes around CB hazards.</p> <p>Another area of focus will be the development of Autonomous Asset Guidance. This capability will be used in conjunction with other capabilities developed under the CBRN Decision Aids portfolio to optimize the use of Autonomous Assets and reduce the burden incurred by the warfighter in order to operate them. This capability will also aim to incorporate, fuse and utilize data from Autonomous Assets to improve and refine other CBRN Decision Aids.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of warning and decision aids for tactical users leveraging the compute resources resident on EUDs. - Initiate the use of augmented reality to provide chemical and biological threat situational awareness in head-mounted visual displays. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.667 Million) transferred to UN2.</p>			
<p>Title: 11) CBRN Situational Awareness</p> <p>Description: To enhance CB Situational Awareness, JSTO will expand the types of threats that can be modeled with hazard assessment capabilities to include fixed-wing and rotary-wing drones of interests. These capabilities will allow for single drones and swarms to be modeled.</p> <p>Virtual Reality (VR) and Augmented Reality (AR) technologies will be leveraged to develop CB focused training and mission rehearsal capabilities that will be integrated into systems widely used by the Joint Force. Virtual training environments will be developed to implement, visualize and account for hazard source terms and plumes generated by transport and dispersion (T&D) models Augmented Reality applications will also be explored for tactical use to maximize warfighter CB situational awareness on the battlefield.</p> <p>JSTO will modernize hazard modeling capabilities by adopting a modular framework and integrating across Service command and control systems to operationalize Reachback support. JSTO will further enhance hazard modeling by creating a seamless indoor-to-outdoor T&D modeling capability and improve urban T&D modeling to support operations in urban and mixed environments. New state-of-the-art computational fluid dynamics modeling techniques and their exploitation of the latest computing resources will be leveraged to increase both speed and accuracy.</p> <p>JSTO will develop CB health effect modeling software and analytic tools to support force readiness and facilitate medical planning against chemical and biological agents. Epidemiological models will be developed that quantify and visualize mission operational</p>	12.330	10.894	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>impacts from exposure to, and spread of, infectious biological threat agents to DoD relevant populations. Additionally, JSTO will leverage Threat Agent Science (TAS) data to enhance capabilities for modeling health effects and host pathogen interactions from exposures to traditional and non-traditional CB agents. This will provide the warfighter with more accurate casualty estimates accounting for human health effects.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Complete development of coupled indoor and outdoor dispersion models for enhanced hazard prediction in urban environments. - Complete field trial to collect validation data for coupled indoor and outdoor dispersion models. - Complete development of next generation littoral and liminal waterborne modeling system. - Continue to enhance CB situational awareness capabilities for integration into Heads up Display (HUD) technologies. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$11.812 Million) transferred to UN2.</p>			
<p>Title: 12) Employment Characterization</p> <p>Description: Employment Characterization studies refine threat assessments and identify potential impacts of indoor and/or outdoor releases of threat agents on CBDP operations, strategy, and capabilities. These studies directly define the Warfighter threat space by determining how chemical and biological agents behave when released. This thrust area reduces risk to the CBDP Enterprise by closing knowledge gaps and informing on the type, extent and magnitude of a potential hazard a warfighter may face in an operational environment.</p> <p>Employment Characterization will: review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and TAS assessment opportunities; continue coordination with international partners to leverage skills and resources; develop closer linkages to hazard prediction modelers to identify knowledge gaps and TAS opportunities; prepare evaluation of potential munitions for applicability to potential future threats based on performance characteristics; and continue chamber tests and operational trials as appropriate for compounds of interest.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to review state of knowledge on agent employment (laboratory and outdoors) to identify gaps and threat agent science assessment opportunities. - Provide munitions evaluation to modelers and stakeholders, and follow with a gap analysis to determine knowledge gaps for future analysis. - Continue studying scale employment methods and feasibility for emerging threat agents. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>	4.943	4.159	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.657 Million) transferred to UN2.				
<p>Title: 13) Environmental Response</p> <p>Description: Environmental Response evaluates CB threats to understand how they will behave in the environment (e.g. persistence, degradation, decomposition), along with the effects of environmental conditions (e.g. ozone, UV, humidity, etc.) on those agents. Studies include evaluations of chemical and biological threat agents on soil, water, and plants, and operational surfaces such as clothing, structures, and equipment. This thrust area reduces risk to the CBDP Enterprise by closing knowledge gaps and informing on the type, extent and magnitude of a potential hazard a warfighter may face in an operational environment. Small-scale laboratory measurements are used to predict the larger-scale behavior and fate of the agents in outdoor and operational settings, while examining agents deposited on operationally relevant substrates refines our understanding of their environmental persistence and hazards. Knowledge obtained from Environmental Response is used to inform operators, predictive model development, and capability development.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue delivering data on fate, persistence, viability and response of priority agents in various environments to inform hazard assessment (for chemical and biological threats). - Continue assessing the impact of environmental factors on threat agent activity (persistence, transport, degradation, resuspension, and decontamination). - Continue to identify and close knowledge gaps associated with the aerosol biology and its implications with the outdoor release of biological threats. - Continue assessing anti-material agents, evaluate the efficacy of these agents, and measure their environmental stability and performance against materials of interest. - Continue environmental stability efforts for toxin and viral threats, including the fundamental characteristics that influence viral stability. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$6.042 Million) transferred to UN2.</p>		5.491	5.548	-
<p>Title: 14) First Look (Chemical and Biological)</p> <p>Description: First Look provides the initial evaluation of known and emerging threat agents to determine their potential hazard to the Warfighter. For both chemical and biological agents, this initial fundamental risk assessment includes evaluation of synthesis and toxicity screening for chemicals and toxins and growth and/or virulence for biological agents as well as production and feasibility of weaponization for all agents. Investments in this area are used to evaluate threat agents as well as develop methods and capabilities to quickly and accurately characterize chemical, biological, and toxin threat agent properties. First Look products/data inform warfighter mission planning,</p>		9.300	9.850	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>requirements generation, capability development, model development, the larger CBDP Enterprise, Intelligence and other government stakeholders about known or emerging agent threats.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue developing innovative laboratory tools and approaches to enable expedient characterization of emerging or novel biological threats (to include highly infectious and novel organisms), including understanding enabling technologies' impact to gene modification/expression and the ability to assess toxin activity. - Continue developing advanced methods for threat agent characterization, including more complex agent mixtures or combinations. - Begin evaluating findings of technological advancement implications to discounted threats study. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$9.850 Million) transferred to UN2.</p>				
<p>Title: 15) Host Response</p> <p>Description: Host Response assesses the human response of exposure to biological and chemical threat agents using operationally relevant exposure scenarios (acute versus chronic) and exposure routes (e.g., .inhalation, dermal, ingestion, etc.) and appropriate assessment methods and models. Data from host response studies are used to develop quantitative exposure limits (e.g. LD50 or ID50) and qualitative information (e.g. mechanism of action) to inform warfighter mission planning, requirements generation, capability development, model development, the larger CBDP Enterprise, Intelligence and other government stakeholders.</p> <p>The program, known as CRISTAL (Computational Rapid Identification and Scientific Threat Analysis) is modernizing to include predictive capabilities for rapidly assessing the human response to chemical and biological threat agents. In addition, host response will be working to close known knowledge gaps associated with traditional threats, including exploring synergistic effects associated with combinatorial agent exposures. Bioavailability of threats that are encapsulated to understand host response differences between exposures to encapsulated versus un-encapsulated threats will be also be assessed.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Build on predictive methods and technologies for both chemical and biological agent characterizations. - Deliver initial operational capacity for predictive toxicological analytical tools linking in silico analysis, in vitro assessments (activity, metabolism, etc), and refining quick turn estimates for emerging chemical threats, and informing follow on toxicological evaluations. - Initiate studies to address host response areas identified by the FY21 gap analysis study for traditional biological agents. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		10.040	15.200	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding (\$14.453 Million) transferred to UN2.				
<p>Title: 16) Technical Surprise</p> <p>Description: Technical Surprise assesses technological advancements for potential implications to the threat space, including agent use and release. Technical Surprise includes horizon scanning to identify potential areas of concern as well as conducts technical assessments of emerging technological advancements (e.g. biotechnology, artificial intelligence, machine learning, quantum computing). This program develops capabilities to evaluate and assess technical enhancements that may alter the nature or magnitude of a threat agent.</p> <p>The technical surprise program will be evaluating emerging technologies and convergence of technologies that improve the ease of threat use and make threats more likely to survive being released. Identify the limitations and barriers associated with synthetic biology and assess the implications. These efforts will identify and assess former technology hurdles that have been lowered or overcome and assess implications of increasing potential threat.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue identifying and assessing technological advancements that will impact the chemical and biological threat space, including potential threats that are not specifically chemical or biological in nature, but have implications to chemical and biological defense capabilities. - Continue a horizon scanning capability to provide situational awareness in assessing technological growth and convergence that can affect the chemical and biological threat space, while keeping abreast to changes in the nature of future threats. - Continue the assessment of synthetic biological tools and other biotechnology developments that can enhance or alter the threat space. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.500 Million) transferred to UN2.</p>		4.000	4.500	-
<p>Title: 17) Dynamic Multifunction Materials for Second Skin</p> <p>Description: This effort supports the Percutaneous Protection. Efforts will utilize responsive technologies to provide chemical biological protective suits that adapt to the environment by synthesizing scaled samples via roll-to-roll manufacture which exhibit materials properties that reduce thermal burden and integrate with current combat garments. These technologies include interpenetrating polymer networks that will change moisture permeability and molecular selectivity on demand, and membranes with higher moisture vapor transfer rates than existing fabrics.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Increase molecular selectivity of responsive interpenetrating polymers towards nerve and blister agents. 		1.972	1.839	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Demonstrate and scale carbon nanotube membrane responsive textiles into garments that increase protection levels in response to chemical weapons agents while preserving moisture vapor transport rate; advance to BA3.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.793 Million) transferred to PT2.</p>				
<p>Title: 18) Lightweight Protective Garments</p> <p>Description: This effort supports the Percutaneous Protection. Efforts will advance garment material and ensemble technologies with new capabilities using integrated garment designs and fabrication for thermal burden reduction, state-of-the-art threat protection technologies, and supporting test methodologies and methods that provide operationally relevant, comparable data on test garments.</p>		0.498	-	-
<p>Title: 19) All-Hazards & Respiratory Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection. Efforts will improve chemical and biological agent protection while maintaining warfighter capability through integrated research on respirator, seams, closures, and new materials; perform early surveys for end-user jury input; frequent user operational evaluation; focus on closed circuit full spectrum respiratory protection.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Transition lightweight protective garment for all hazards environments to Uniform Integrated Protection Ensemble Family of Systems Program of Record. - Complete development of systems that provide chemical biological respiratory protection technologies in support of tactical all hazard, full spectrum respiratory protection system. - Develop next generation respiratory protection technology in the form of a low-burden, non-contact powered respirator with novel filter designs that integrates with Warfighter technologies and reduces encumbrance. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$1.482 Million) transferred to PT2.</p>		2.984	1.380	-
<p>Title: 20) Multifunctional Materials for Protection</p> <p>Description: This effort supports the Respiratory and Ocular Protection, Percutaneous Protection, Expeditionary Collective Protection, Materiel Contamination Mitigation, and Personnel Contamination Mitigation. Efforts will discover, develop and integrate novel, reactive/catalytic materials and scale material manufacturing with maximum sorption and reactivity, and characterize materials using state-of-the-art in operando and ambient pressure spectroscopies, for eventual integration into next generation decontaminants, coatings, filters, and protective garments that reactively decontaminate chemical warfare agents.</p>		3.107	5.677	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
<p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to engineer reactive/catalytic nano-structure materials from basic research efforts for chemical agent destruction, to facilitate air purification enhancement. - Continue to integrate engineered reactive/catalytic nano-structure materials into filters, decontaminants, and textiles to assess materials in an operationally-relevant environment for personnel decontamination. - Develop self-decontaminating, reusable protective garments of composite textiles with a reactive barrier, improved protection, and reduced thermal burden/life-cycle costs for advancement to the BA3 level. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.478 Million) transferred to PT2 and MT2.</p>			
<p>Title: 21) Personnel Decontamination</p> <p>Description: This effort supports the Personnel Contamination Mitigation. Efforts will develop decontaminants for decontamination of unbroken skin with lower lifecycle costs and storage constraints and determination of time, efficacy and logistics burdens to warfighters for mass casualty decontamination. Decrease Warfighter burden in the event of a CWA exposure by identifying science and technology gaps in the mass personnel decontamination process as well as possible substitutions for current approved personnel decontamination formulations.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue to develop and assess physical removal technologies for potential replacement of Reactive Skin Decontamination Lotion in support of the Next Generation Personnel Decontamination Program of Record. - Continue to integrate new dry decontamination into a mitt form-factor and determine science and technology challenges within process and procedure improvements. - Develop methodologies and procedures to for military working dog decontamination. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.692 Million) transferred to MT2.</p>	1.177	1.180	-
<p>Title: 22) Air Purification Enhancements</p> <p>Description: This effort supports the Expeditionary Collective Protection (CP). Existing CP systems have high life cycle costs driven by maintenance and limited service life. JSTO efforts will focus on optimizing and extending filter life to reduce lifecycle costs while maintaining or improving protection.</p> <p>FY 2022 Plans:</p>	0.881	0.393	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) CB2 / Chemical Biological Defense (Applied Research)

B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
- Continue integration of the full range of nontraditional agents, including other emerging threats into the air purification enhancement portfolio and testing under relevant environmentally-relevant conditions. - Continue efforts for novel filtration against nontraditional agents and other emerging threats in ColPro and other large-scale filter systems in support of the Collective Protection Modernization Program of Record.			
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.662 Million) transferred to PT2.			
Accomplishments/Planned Programs Subtotals	95.517	104.362	-

C. Other Program Funding Summary (\$ in Millions)											
Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• CB3: Chemical	26.844	26.950	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	53.794
<i>Biological Defense (ATD)</i>											
• MT3: Mitigate (ATD)	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing
• PT3: Protect (ATD)	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing
• UN3: Understand (ATD)	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program										Date: April 2022		
Appropriation/Budget Activity 0400 / 2					R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)				Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)			
COST (\$ in Millions)	Prior Years	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
TM2: Techbase Medical Defense (Applied Research)	-	93.525	105.594	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	199.119

A. Mission Description and Budget Item Justification

Project TM2 provides for applied research for innovative technology approaches to advance medical systems designed to rapidly identify, diagnose, prevent, and treat disease due to exposure to chemical and biological threat agents. In FY2023, the CBDP RDT&E Projects have been restructured to align to the CBDP portfolio. TM2 thrust areas in FY2022 progress to the Mitigate (MT2), Protect (PT2), and Understand (UN2) portfolios. This restructuring is intended to provide standardization and alignment across CBDP research, development and acquisition efforts.

Individual efforts in this Project include:

- Core science efforts in Medical Chemical, Medical Biological, Diagnostics, and Medical Countermeasures.
- Supports applied research for the investigation of new medical countermeasures to include prophylaxes, pretreatments, antidotes, skin decontaminants, and therapeutic drugs against identified and emerging biological and chemical warfare agents.
- Medical Science and Technology (S&T) efforts in this Budget Activity refine promising medical initiatives identified in Budget Activity 1, resulting in the development of countermeasures to protect against and treat the effects of exposure to chemical and biological (CB) agents.
- Diagnostic research focuses on providing high quality data closer to the point-of-need comprising device innovation, panels of biomarkers driven by bioinformatics, and epidemiological modeling tools.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2021	FY 2022	FY 2023
Title: 1) Chemical Diagnostics	1.665	1.554	-
Description: Provide innovative and integrated capabilities to the Warfighter that are able to diagnose threats across the chemical spectrum. Enhance force protection by investing in diagnostics for exposure to traditional and nontraditional Chemical Warfare Agents (CWAs), including pharmaceutical based agents (PBAs). Leverage the development of a chemical diagnostic that monitors blood, indicating whether a Warfighter has been exposed to nerve agents within minutes.			
FY 2022 Plans:			
- Initiate the development to adapt the CHEMDX platform to simultaneously measure organophosphate nerve agent and fentanyl exposure to rapidly inform whether an individual has been exposed to a high probability incapacitant.			
- Complete the development of new and optimized lab-based assays, field forward sampling, and IVD technologies to verify human exposures to OP and HD.			

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
- Continue the development of strategies to address portable ultra-low detection of opioids.				
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$0.693 Million) transferred to UN2.				
Title: 2) Diagnostic Building Blocks		5.644	4.446	-
Description: Develop novel, state of the art capabilities that lay the foundation for modernizing other areas within the diagnostics portfolio. This includes exploiting areas such as synthetic biology and chemistry to develop novel and rapid diagnostic tests for utilization in the event of an outbreak of an unknown threat. Invest in efforts that lead to accelerated assay development timelines and optimized test parameters through leveraging artificial intelligence (AI) and machine learning (ML) to allow us to quickly pivot and develop assays for emerging threats and speed up development to days instead of weeks.				
FY 2022 Plans: - Complete the development of protocols for generating SYMBAs that are sensitive and specific and can be applied to various diagnostic platforms, supporting open-architecture capabilities				
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$3.466 Million) transferred to UN2.				
Title: 3) Emerging Threats		7.439	4.110	-
Description: Push beyond the boundaries of the traditional threat list in the field of diagnostics to better prepare for surprise. Development of diagnostic systems that leverage novel approaches to characterize pathogen or host response and can identify the classification of threat (e.g., bacterial vs viral) from an unknown sample. Invest in diagnostic tests that enable the delivery of actionable information, such as administering the appropriate medical countermeasure (e.g. antibiotic, antiviral, vaccine), by a medic or primary care provider greatly improves turnaround time for soldier wellness and return to duty.				
FY 2022 Plans: - Complete research characterizing AMR and AST mechanisms in Burkholderia pseudomallei. - Complete and validate an improved diagnostic development pipeline for hard to detect pathogens and transition to JPEO. - Complete the development of a comprehensive reference guide that will enable evidence based decision processes that drive the development of current and future diagnostic technologies and transition to JPEO. - Complete evaluation efforts for adapting an FDA approved biomarker platform for diagnosis of human TBI to a platform for diagnosis of brain injury resulting from the encephalitic alphaviruses. - Continue efforts on several complementary approaches to address challenges in toxin diagnosis at the POC.				

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue the development of a universal blood sample preparation platform to be compatible with several diagnostic systems.</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$2.773 Million) transferred to UN2.</p> <p>Title: 4) Bacterial/Viral/Toxins/Broad Spectrum Prophylaxis</p> <p>Description: The ultimate protection of the Warfighter is achieved by pretreating the Warfighter to withstand any biological threat with no adverse side effects from the pretreatment. Such pretreatment would enable the Warfighter to work in a less restrictive environment, absent of any personal protective equipment, facilitating the Warfighter to operate at peak performance. Investments in this Program Element support innovative concepts in prophylaxis that support needs specific to the warfighter such as broad spectrum protection, rapid onset to protection, fewer doses required, no cold chain required, and needle-free administration.</p> <p>FY 2022 Plans:</p> <p>Bacterial:</p> <ul style="list-style-type: none"> - Complete the non-clinical animal studies for two back-up Burkholderia vaccine candidates. Candidates will proceed in development under BA3 funding if results indicated candidates are efficacious, otherwise, efforts will be terminated. - Continue development of Burkholderia monoclonal antibodies. - Continue non-clinical animal immunogenicity and efficacy studies for a Tularemia subunit. - Continue efforts in enabling science and NHP efficacy model development for Q fever. - Continue Q Fever vaccine prototype testing and candidate down selection. - Continue to evaluate protective efficacy of Anthrax vaccines against novel Bacillus anthracis strains. <p>Viral:</p> <ul style="list-style-type: none"> - Initiate non-clinical animal studies for the Inactivated Western, Eastern, and Venezuelan Equine Encephalitis (WEVEE) vaccine candidate. - Initiate non-clinical animal studies for the Trivalent Western Equine Encephalitis and Venezuelan Equine Encephalitis (WEEVEE) DNA vaccine. - Complete initial development of alphavirus mAbs against VEEV, EEEV, and WEEV, epitope identification and mAb generation. <p>Project will continue utilizing BA3 funding.</p> <ul style="list-style-type: none"> - Conduct nonclinical safety and efficacy studies for the Marburg Virus (MARV) DNA vaccine. - Down-select between alternative delivery devices for DNA vaccine delivery. <p>Toxins:</p> <ul style="list-style-type: none"> - Conduct epitope identification and mAbs generation against several marine toxins. 		24.622	29.778	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<ul style="list-style-type: none"> - Continue to develop novel antitoxin technologies including exploring the use of cell membrane coated nanospheres. - Continue evaluation of toxins and antitoxin prophylaxis in animal models. - Continue to develop functional assays to determine biological activity for various toxins. <p>Broad Spectrum:</p> <ul style="list-style-type: none"> - Continue novel pan virus nanosphere platform development to address emerging threats, explore additional applications of nanosphere technology to include emerging toxins and bacterial threats. - Explore additional strategies and platforms for broad spectrum protection to address protection against emerging threats. - Evaluation of next generation adjuvants for use in biodefense vaccines. - Initiate nonclinical evaluation of multivalent vaccine against arenaviruses. - Continue to qualify/validate MIMIC for use in evaluation of pulmonary responses to biodefense vaccines. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$26.699 Million) transferred to PT2.</p>				
<p>Title: 5) Chemical Reactive Ocular Wound and Dermal Therapeutics (CROWD)</p> <p>Description: Focuses on therapeutic strategies to effectively treat CWA contamination on wounds, eyes, and large areas of intact skin. This effort involves the development of products capable of removing or neutralizing CWAs from those routes of exposure, to decrease the toxic load of agent and allow optimal effectiveness of other systemic therapeutics.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Determination of dosing strategies for use of candidate products in traumatic wounds. - Perform advanced preclinical studies to validate safety and efficacy in support of clinical trials. - Assessment of candidate product readiness for advanced development. - Continue refinement of manufacturing and stability. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$6.351 Million) transferred to MT2.</p>		3.126	6.679	-
<p>Title: 6) Enabling Science</p> <p>Description: Protection of the Warfighter against Chemical Warfare Agents (CWAs) to maintain force lethality is the ultimate goal of the Enabling Sciences portfolio. The portfolio leverages innovative approaches and emerging technologies to support modernization of chemical medical countermeasure (cMCM) pipeline. The portfolio is designed to develop and deploy cMCMs more rapidly to the warfighter.</p>		8.137	10.930	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>Portfolio elements include: 1) development of Artificial Intelligence/Machine Learning (AI/ML) tools to more efficiently identify cMCMs and assess their safety and efficacy for regulatory submission; 2) AI/ultra-high throughput screening-based sampling of large chemical spaces with the aim of providing broad spectrum cMCMs with improved efficacy and selectivity, minimal toxicity, and decreased expense and fielding times to the warfighter; 3) development of technologies to deliver MCMs across the blood brain barrier (BBB) into the brain; 4) maturation of cMCMs with innovative mechanisms of actions; and 5) development of well characterized or FDA qualified animal models, as needed, to support cMCM discovery and development under the FDA animal rule.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Employ AI-based computational toxicology and drug design system incorporating machine learning algorithms to streamline drug design. - Continue to maintain databases of both high throughput screening and ADME/T data for drug candidates. - Continue to perform select animal and safety studies for lead therapeutic candidates, including anticholinergics, for treatment of CWAs. - Continue to develop encapsulation and shuttle technologies that will deliver the 2-PAM payload across the BBB. - Continue to support the therapeutic candidate pipeline. - Perform follow on in vitro and in vivo safety and efficacy studies to support the down selection of high throughput screening hits to leads. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$13.134 Million) transferred to MT2.</p>				
<p>Title: 7) Pharmaceutical Based Agents (PBAs)</p> <p>Description: Focuses on therapeutic strategies to effectively minimize injuries resulting from exposure to Pharmaceutical Based Agents (PBAs). This effort involves the evaluation FDA approved therapeutics for operational use, as well as generation of novel drug products to enhance level of protection and/or operational utility for the Warfighter. Efforts in this area are designed to develop drug candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue development of novel opioid therapeutics which will allow current pain management doctrine. - Continue operational assessment of FDA approved drug products to inform MCM timing and sequence in the event of a known or unknown chemical exposure. 		6.564	7.390	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
<p>- Continue to assess drug products for use against other priority PBA emerging threats (e.g., non-opioids)</p> <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$5.586 Million) transferred to MT2.</p>				
<p>Title: 8) Reactivators of AChE as Therapeutics (ReACT)</p> <p>Description: The Warfighter requires rapid acting medical countermeasures (MCMs) to counter adverse effects from exposure to Nerve Agents (NAs) and maintain force lethality. This effort involves the development of improved therapies for acetylcholinesterase enzyme reactivation. Efforts in this area are designed to develop potential candidates that will ultimately be submitted for Food and Drug Administration (FDA) licensure or to identify previously licensed products for new uses in the treatment of chemical warfare casualties.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Test the safety and efficacy of candidate resurrectors of inhibited acetylcholinesterase in vivo in animal models. - Down select generated chemical libraries to the most promising broad spectrum therapeutic candidates for follow on safety and efficacy assessments. - Continue drug formulation efforts for MCMs with a longer shelf-life and with feasibility of an auto-injector containing material and chemical composition. - Continue development of current and screening for novel broad spectrum cholinesterase reactivators that are effective in the brain. <p>FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.279 Million) transferred to MT2.</p>		7.501	5.262	-
<p>Title: 9) Bacterial Therapeutics</p> <p>Description: Discover and develop therapeutic countermeasures to mitigate the effects of known and emerging bacterial threats to the warfighter.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to discover and develop traditional (small molecule inhibitors) and non-traditional (phage therapies, antimicrobial peptides, immunomodulators, and host-directed therapies) therapeutic candidates to existing and emerging bacterial threats. - Complete the development of formulations for existing antibiotic therapies that increase efficacy against bacterial pathogens and initiate proof of concept animal studies. - Continue small animal proof of concept testing to identify novel/nontraditional therapies against all pathogens. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p>		10.915	14.456	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022		
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B. Accomplishments/Planned Programs (\$ in Millions)		FY 2021	FY 2022	FY 2023
Funding transferred to a new Project due to budget restructure. FY23 funding transferred to MT2. Beginning FY23, Viral/Bacterial/Toxin Therapeutics bullets will be consolidated into Biological Warfare Defense Therapeutics.				
<p>Title: 10) Viral Therapeutics</p> <p>Description: Discover and develop therapeutic countermeasures to mitigate the effects of known and emerging viral threats to the warfighter.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continuation of testing and development of biologics and small molecules targeting viral threats. - Continuation of the discovery and down-selection of additional broad-spectrum, direct-acting and host-directed antivirals - Initiate new investments in the discovery and down-selection of additional broad-spectrum, direct-acting and host-directed antiviral candidates for existing and emerging threats. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding transferred to MT2. Beginning in FY23, the Viral/Bacterial/Toxin Therapeutics bullets will be consolidated into Biological Warfare Defense Therapeutics.</p>		13.599	14.457	-
<p>Title: 11) Toxin Therapeutics</p> <p>Description: Discover and develop therapeutic countermeasures to protect the warfighter against biotoxin threats.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue evaluation of broad-spectrum, small molecule compounds and biologics for efficacy in the treatment and recovery from intoxication by BoNT. <p>FY 2022 to FY 2023 Increase/Decrease Statement:</p> <p>Funding transferred to a new Project due to budget restructure. FY23 funding transferred to MT2. Beginning FY23, Viral/Bacterial/Toxin Therapeutics bullets will be consolidated into Biological Warfare Defense Therapeutics.</p>		0.250	0.250	-
<p>Title: 12) Nerve Agent Prophylaxis/Pretreatments</p> <p>Description: Develop pretreatments and prophylactics that counter chemical warfare agents, including organophosphorus nerve agents (OPNA), using targeted and innovative S&T efforts that will offer broad-spectrum protection, flexible route of administration, lower dose requirements, and reduced operational and logistical burden. The use of these MCMs will protect the lives and effectiveness of our Warfighters, thus maintaining force strength and force capability.</p> <p>FY 2022 Plans:</p> <ul style="list-style-type: none"> - Continue efforts to develop catalytic enzymes for use against selected, priority NTAs. 		4.063	3.282	-

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program		Date: April 2022
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B. Accomplishments/Planned Programs (\$ in Millions)	FY 2021	FY 2022	FY 2023
- Continue expanded pre-clinical studies of lead catalytic scavengers to support future investigative new drug (IND) filing. - Continue efforts to develop capability for rapid development of medical countermeasures. - Continue efforts to explore and further develop novel non-enzyme nerve agent prophylaxis. - Continue new approaches to identify pretreatment and prophylaxis against multiple classes of NTAs and emerging chemical threats.			
FY 2022 to FY 2023 Increase/Decrease Statement: Funding transferred to a new Project due to budget restructure. FY23 funding (\$4.158 Million) transferred to PT2.			
Accomplishments/Planned Programs Subtotals	93.525	102.594	-

	FY 2021	FY 2022
Congressional Add: Biological Warfare Defense Therapeutics FY 2022 Plans: For PUL 042 (Burkholderia, Tularemia), proof of concept small animal efficacy studies will be completed with options for non human primate pharmacokinetics studies, and GMP manufacturing. The candidate will then be ready to transition to advanced development. This is a host directed therapeutic and fits with our broad spectrum strategy for MCMs. - Continue non-clinical animal immunogenicity and efficacy studies for a Tularemia subunit.	-	3.000
Congressional Adds Subtotals	-	3.000

C. Other Program Funding Summary (\$ in Millions)

Line Item	FY 2021	FY 2022	FY 2023 Base	FY 2023 OCO	FY 2023 Total	FY 2024	FY 2025	FY 2026	FY 2027	Cost To Complete	Total Cost
• MT2: Mitigate (Applied Research)	0.000	0.000	75.411	-	75.411	71.705	68.483	64.502	70.651	Continuing	Continuing
• PT2: Protect (Applied Research)	0.000	0.000	58.758	-	58.758	59.338	59.855	61.517	63.612	Continuing	Continuing
• UN2: Understand (Applied Research)	0.000	0.000	122.028	-	122.028	117.683	105.509	101.577	100.929	Continuing	Continuing
• EN3: Enabling Investments (ATD)	0.000	0.000	42.590	-	42.590	43.197	43.198	44.449	44.449	Continuing	Continuing
• MT3: Mitigate (ATD)	0.000	0.000	84.476	-	84.476	87.722	86.475	83.109	84.066	Continuing	Continuing
• PT3: Protect (ATD)	0.000	0.000	35.319	-	35.319	32.804	42.272	41.264	41.264	Continuing	Continuing
• TM3: Techbase Medical Defense (ATD)	134.162	137.691	0.000	-	0.000	0.000	0.000	0.000	0.000	0.000	271.853

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Exhibit R-2A, RDT&E Project Justification: PB 2023 Chemical and Biological Defense Program	Date: April 2022
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Appropriation/Budget Activity 0400 / 2	R-1 Program Element (Number/Name) PE 0602384BP / CHEMICAL/BIOLOGICAL DEFENSE (APPLIED RESEARCH)	Project (Number/Name) TM2 / Techbase Medical Defense (Applied Research)
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C. Other Program Funding Summary (\$ in Millions)

<u>Line Item</u>	<u>FY 2021</u>	<u>FY 2022</u>	<u>FY 2023</u> <u>Base</u>	<u>FY 2023</u> <u>OCO</u>	<u>FY 2023</u> <u>Total</u>	<u>FY 2024</u>	<u>FY 2025</u>	<u>FY 2026</u>	<u>FY 2027</u>	<u>Cost To</u> <u>Complete</u>	<u>Total Cost</u>
• UN3: <i>Understand (ATD)</i>	0.000	0.000	76.022	-	76.022	74.348	74.412	77.884	66.014	Continuing	Continuing

Remarks

D. Acquisition Strategy

N/A